REMARKS

Claims 23, 25, and 27-29 are pending in this application. Claims 23, 25, and 27-29 have been rejected. Claim 23 has been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested.

I. Rejection of Claims under 35 U.S.C. §112, second paragraph

The Examiner has rejected claims 23, 25, 27-29 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. It is suggested that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed had possession of the invention.

Applicants claims as amended recite methods of using rabbit carboxylesterase comprising SEQ ID NO: 21. It is suggested that use of the precarboxylesterase in the claimed methods constitutes new matter.

Applicants respectfully disagree with this rejection.

However, in an earnest attempt to facilitate prosecution of this case, Applicant has amended claim 23 in accordance with the Examiner suggestion to recite "a rabbit carboxylesterase

recombinantly produced by expressing a polynucleotide encoding SEQ ID NO:21. Support for this amendment is found throughout the application and at page 11, line 22.

Accordingly, withdrawal of this rejection under 35 U.S.C. § 112, second paragraph is respectfully requested.

II. Rejection of Claim 25 under 35 U.S.C. §103(a)

Claims 23, 25 and 27- 29 are rejected under 35 U.S.C. §103(a) as being anticipated by Senter et al. (Reference AG of Applicants PTO-1449, herein after referred to as Senter), in view of Danks et al. (Reference AB of Applicants PTO-1449, herein after referred to as Danks) and Satoh et al. (Reference BA of Applicants PTO-1449, herein after referred to as Satoh).

The Examiner suggests that Senter teach methods of increasing the activation of the prodrugs Paclitaxel and camptothecin (CPT-11) to active drugs in human and mouse tumor cells by the administration of rat serum carboxylesterase following administration of the prodrug. Danks is suggested to teach that a recombinant rabbit liver carboxylesterase sensitizes human tumor cells to the prodrug CPT-11. Satoh is suggested to describe the specific activity of a variety of mammalian carboxylesterases for the activation of CPT-11 to SN-38, and show

that rabbit liver carboxylesterase has one of the highest specific activities for this substrate and that the specific activity of the rabbit enzyme is four times greater than that of the rat enzymes.

The Examiner suggests that it would have been obvious for one of skill in the art to use the recombinant rabbit enzyme of Danks in the methods of Senter, as Satoh teach that the rabbit enzyme has a higher specific activity of any of the rat enzymes. Applicants respectfully disagree with this rejection.

To establish a *prima facie* case of obviousness under 35 U.S.C. 103(a) three basic criteria must be met. MPEP § 2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art must teach or suggest all of the claim limitations.

First, it is respectfully pointed out that the Danks reference is an improper prior art reference as it is a publication by the inventors and published less than one year before the application filing date. Therefore, the Danks reference is not by another nor was it published more than twelve

months prior to this application for patent both of which are required under the MPEP for a document to be considered prior art.

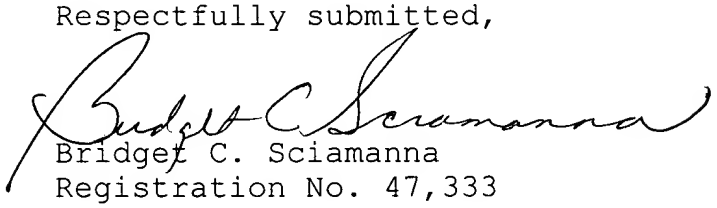
The other two recited references (Senter and Satoh) fail to meet the three basic criteria required to prove a *prima facie* case of obviousness under 35 U.S.C. 103(a)with respect to the instant claimed invention. Senter teaches methods of increasing the activation of the prodrugs Paclitaxel and camptothecin (CPT-11) to active drugs in human and mouse tumor cells by the administration of rat serum carboxylesterase. Satoh teach that the rabbit enzyme has a higher specific activity of any of the rat enzymes. There is no teaching or suggestion in either Senter nor Satoh that the rabbit carboxylesterase recombinantly produced by expressing a polynucleotide encoding SEQ ID NO:21 as that claimed by the present invention would provide any advantage in forming an active drug. Thus the prior art does not teach or suggest all of the claim limitations.

Withdrawal of this rejection is respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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